Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the efficacy of intravenous paracetamol versus intravenous dexamethasone and intravenous morphine for the emergency department treatment of acute migraine headache

Protocol summary

Summary

Objectives: To compare the analgesic effect of intravenous paracetamol (apotel) with the common therapies such as dexamethasone and morphine. Design, Setting, conduct and intervention: The study sample will divides into three randomly groups. In the first group after the diagnosis, 1 gram intravenous acetaminophen will be soluted in 100 cc normal saline and will infused. In the second group, morphine with 0.1 mg/kg dosage will be infused. In the third group 8 mg dexamethasone will be infused. Inclusion criteria:Age between 18 and 60 year old without any history of neurologic disorder with at least one experience of migraine headache and 4 criteria of 12 criteria of Vascular symptoms. Exclusion criteria : pregnancy; history of neurologic disorder; patients without self consent; Body temperature more than 37.7 C; diastolic blood pressure more than 105 mm Hg. Variables: Pain severity before starting treatment, 10,20,30 and 60 minutes and 24 hours after starting treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405217327N4**
Registration date: **2014-09-30, 1393/07/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-09-30, 1393/07/08

Registrant information

Name

Samad Shams Vahdati

Name of organization / entity

Tabriz University of Medical Scinces

Country

Iran (Islamic Republic of)

Phone

+98 41 1658 1401

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Recruitment status

Recruitment complete

Funding source

Student Research Committee,Tabriz University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of intravenous paracetamol versus intravenous dexamethasone and intravenous morphine for the emergency department treatment of acute migraine headache

Public title

Comparison of the efficacy of intravenous paracetamol versus intravenous dexamethasone and intravenous morphine for the emergency department treatment of acute migraine headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : the patients between 18 and 60 year old without any history of neurologic disorder with at least one experience of migraine headache and 4 criteria of 12 criteria of Vascular symptoms. Exclusion criteria : pregnancy; history of neurologic disorder; patients without self consent; Body temperature more than 37.7 C; diastolic blood pressure more than 105 mm Hg.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **270**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Subjects will be randomized by Random.com website.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Scinces Ethic Committe

Street address
Central building number 2, Tabriz University of Medical Scinces, Golgasht street, Tabriz

City
Tabriz

Postal code

Approval date
2014-02-05, 1392/11/16

Ethics committee reference number
5/4/9871

Health conditions studied

1

Description of health condition studied
Acute migraine headache

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Pain intensity of the acute migrane head ache

Timepoint
Before treatment, 10 minutes after the begining of treatment, 20 minutes after the begining of the treatment, 30 minutes after the begining of the treatment, 24 hours after the begining of the treatment.

Method of measurement
Visual analoge score, Intensity of the pain in proportion to millimetr from 0 to 100 will be measured.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1 gram acetaminophen will be soluted in 100 cc normal saline and will be infused in 10 minutes as a single dose. Drug name: Apotel, 1 g/6.7ml Chemical compound: Acetaminophen Company: Uni Pharma S.A country: Greece

Category
Treatment - Drugs

2

Description
Control group: Morphine with 0.1 mg/kg dosage will be soluted in 100 cc normal saline and will be infused in 10 minutes as a single dose in order to simulation. Drug name: Morphin, 10 mg/ml Injection Chemical compound: Morphine sulfate company: Darou Pakhsh-Iran Country: Iran

Category
Treatment - Drugs

3

Description
Control group: 8 milligram dexamethasone will be soluted in 100 cc normal saline and will be infused in 10 minutes as a single dose in order to simulation. Drug name: Dexamethasone, 8 mg/ml Chemical compound: Dexamethasone Company: Raha Co Isfahan-Iran Country: Iran

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz Imam Reza Hospital

Full name of responsible person
Dr.Samad Shams Vahdati

Street address

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Student Research Committee

Full name of responsible person
Robab Irani

Street address
Research Development Building, University Street.

City
Tabriz

Grant name
-

Grant code / Reference number
-

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Student Research Committee

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr.Samad Shams Vahdati

Position
Assistant Professor of Emergency Medicine

Other areas of specialty/work

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Position
Assistant Professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty